

ADMINISTRATIVE RECORD

1077363 - R8 SDMS



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 23 2007

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable Max Baucus
United States Senate
Washington, DC 20510

Dear Senator Baucus:

As you requested at the April 5, 2007, hearing in Libby, Montana, enclosed please find the July monthly report on the status of toxicological work in support of the Libby clean up.

If you have any questions, please contact me, or your staff may contact Amy Kover in the U.S. Environmental Protection Agency's Office of Congressional and Intergovernmental Relations at (202) 564-0555.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Bliley", written over a horizontal line.

Christopher P. Bliley
Associate Administrator

Enclosure

Status of Toxicity Assessment and Analytical Methods Support Studies for Libby Amphibole July 2007

Toxicity Assessment Studies

EPA Region 8 Libby Amphibole Reference Concentration (RfC) Development—EPA scientists have evaluated data from University of Cincinnati researchers (including discussions at the July 23-24 meeting in Denver) and with the Scotts Company which indicate noncancer health effects in workers from a plant in Marysville, Ohio. EPA is working together with the primary researchers to refine the dataset and most recently has received additional historical exposure measurements which may better inform the ongoing analysis. These data will be evaluated and considered as EPA develops a Reference Concentration (RfC) for Libby Amphibole.

NCEA Libby Amphibole Cancer Assessment—EPA has executed an interagency agreement with NIOSH to establish a collaborative effort such that the most up-to-date mortality data on individuals exposed to Libby amphibole can be used in the cancer assessment. Data from the recent NIOSH update of the Libby, MT worker cohort will be evaluated for possible use in a quantitative risk assessment. The analysis may take from several months to a year to complete, based on what complexities arise in analysis of the data.

EPA Region 8/USGS Preparation of Libby Testing Material—USGS has begun collection activities for the Libby amphibole material. USGS continues to work closely with the Region 8 and NHEERL research team to ensure that the preparation and characterization material will meet the needs of the animal toxicity studies.

EPA Region 8 Characterization of Fiber Size Distribution in Libby Vermiculite—Plans are being developed to begin this study in this fiscal year. Region 8 will solicit support from USGS to conduct this study.

NHEERL Dosimetry Model Development and Simulation Studies—The detailed project plan has been reviewed by external peer reviewers and Libby Area Technical Assistance Group. Detailed responses to reviewers and revised plans have been completed and were approved on August 1.

NHEERL In vitro Dissolution Assays—The detailed project plan has been reviewed by external peer reviewers and Libby Area Technical Assistance Group. Detailed responses to reviewers and revised plans have been completed and were approved on August 1. A meeting was held in Denver on July 18-19 to design the approach for analyzing the leachates generated from these studies. A Standard Operating Procedure (SOP) utilizing the TEM method is currently under development.

NHEERL In Vitro Toxicity Endpoints—The detailed project plan has been reviewed by external peer reviewers and Libby Area Technical Assistance Group. Detailed responses to reviewers and revised plans have been completed and were approved on August 1. A meeting was held in Denver on July 18-19 to design the approach for analyzing the cell culture samples generated from these studies. An SOP utilizing the TEM method is currently under development.

NHEERL Comparative Toxicology in Mice and Rats—The detailed project plan has been reviewed by external peer reviewers and Libby Area Technical Assistance Group. Detailed responses to reviewers and revised plans have been completed and were approved on August 1. A meeting was held in Denver on July 18-19 to design the approach for analyzing the tissues generated from these studies. An SOP utilizing the TEM method is currently under development.

NHEERL Inhalation Toxicology in Rats—The detailed project plan has been reviewed by external peer reviewers and Libby Area Technical Assistance Group. Detailed responses to reviewers and revised plans have been completed and were approved on August 1. A meeting was held in Denver on July 18-19 to design the approach for analyzing the tissues generated from these studies. An SOP utilizing the TEM method is currently under development.

EPA Region 8/NCEA New Epidemiologic Information from Libby Montana Cohort—A meeting was held in Denver on July 23-24 with representatives from EPA, ATSDR, NIOSH, CARD clinic, University of Montana, University of Cincinnati, Mount Sinai School of Medicine, Karmanos Cancer Institute, Libby Area Technical Assistance Group, and other experts to identify potential epidemiologic studies and analyses that might be of value to support the Libby Toxicity Assessment. Follow-up discussions amongst government risk assessors in August will consider which of these may be of greatest value to developing a timely risk assessment.

EPA Region 8/NCEA New Epidemiologic Information from Other Cohorts—A meeting was held in Denver on July 23-24 with representatives from EPA, ATSDR, NIOSH, CARD clinic, University of Montana, University of Cincinnati, Mount Sinai School of Medicine, Karmanos Cancer Institute, Libby Area Technical Assistance Group, and other experts to identify potential epidemiologic studies and analyses that are needed to support the Libby Toxicity Assessment. EPA is currently identifying possible study populations as well as existing data and ongoing studies from other locations that received Libby materials. Follow-up discussions amongst government risk assessors in August will consider which of these may be of greatest value to developing a timely risk assessment.

OSWER Interim Risk Methodology for Quantification of Cancer Risk from Inhalation—The current draft methodology is undergoing internal review by EPA scientists. Once revised, a draft document will be submitted to EPA's Science Advisory Board for a technical consultation regarding the risk methodology.

Analytical Methods Studies

EPA Region 8 Filter Verification Studies

The detailed project plan is under development and is currently in review by internal reviewers.

EPA Region 8 Low-Level Soil Method Development

Plans are being developed to begin this study in fiscal year 2008.

EPA Region 8 Comparison Direct & Indirect Preparations

Plans are being developed to begin this study in fiscal year 2008.

EPA Region 8 Ambient Air Collection Method Verification

Plans are being developed to begin this study in fiscal year 2008.

Acronyms

ATSDR- Agency for Toxic Substances and Disease Registry

CARD – Center for Asbestos Related Disease

NCEA – EPA National Center for Environmental Assessment

NHEERL – EPA National Health and Environmental Effects Research Laboratory

NIOSH- National Institute for Occupational Safety and Health

OSWER – EPA Office of Solid Waste and Emergency Response

USGS – US Geological Survey